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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,078	02/13/2004	Robert I. Connelly	4634	4130

1609 7590 03/18/2010

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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

03/18/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/777,078

**Applicant(s)**

CONNELLY ET AL.

**Examiner**

MATTHEW F. DESANTO

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Idriss (USPN 4838887).
3. Idriss discloses an infusion pump, with a housing, a reservoir containing a supply of said fluid, a first flow channel in fluid communication with said reservoir, a delivery cannula and a resealable port. (Figure 3, 5B and entire reference)
4. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinicke et al. (USPN 4715852).

Reinicke et al. discloses a medical infusion pump comprising a housing (20), a reservoir (30) under pressure by a spring element, a first and second flow channel (42,48), a delivery cannula (126) in fluid communication with the first and second flow channel and a resealable port (28) (Figure 1-4, 9, 10 and entire reference).

5. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris (USPN 4,548,607).

Harris discloses a medical infusion pump comprising a housing, a reservoir fluidly connected to a delivery cannula (12), a primary restrictor (20), a bolus restrictor channel

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with a bolus button (21) and a bolus exit channel connected to a spring check valve (81) (Figure 1-4, 9, 10 and entire reference).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratoska et al. (USPN 5445616), and further in view of Pike et al. (USPN 5009251) and further in view of Harris (USPN 4548607).

Kratoska et al. discloses a medical pump with a housing, a reservoir, a delivery cannula, a spring, a resealable port and a flow regulator, but fails to describe the flow regulator in detail. (Figure 1,2 and entire reference)

Pike et al. discloses a fluid flow controller used for regulating the fluid flow in medical devices, wherein the fluid regulator comprises many channels and the channels have a plurality of sections and a plurality of nodes. The regulator has a selectable knob, which determines the rate of fluid control by closing fluid channels throughout the device. (Figure 3,4,5,8, 9 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Kratoska et al. with the fluid regulator of Pike et al., because Kratoska et al. discloses a flow regulator (30), "which can be any type of flow restriction device," (Kratoska - Column 3, line 64-67) with his claimed

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invention, therefore allowing one of ordinary skill in the art to make a obvious modification to combine the teachings of Pike et al.'s flow regulator with the disclosed invention of Kratoska et al. The reason for using Pike et al. disclosed invention is because it is cheap and very accurate in controlling the amount of liquid infused. (Pike - Column 1, lines 32-46).

For claims 22-24

Kratoska et al. and Pike et al. disclosed the claimed invention except for the bolus button.

Harris discloses a bolus button connected to restrictor channel and a bolus exit channel and wherein the bolus the bolus restrictor channel further comprises a check valve and a flow restrictor channel.

At the time of the invention it would have been obvious to combine Kratoska et al. and Pike et al. with Harris because Harris teaches a manually actuated micro pump which is convenient to operate and economical to manufacture, therefore adding the bolus button to the disclosed invention would allow for an easy and convenient way to administer a large dose of the drug to the patient.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,702,779.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a housing, reservoir, a primary restrictor, a delivery cannula, a bolus restrictor, a bolus ext, a bolus button and a rate selector.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew DeSanto  
/Matthew F DeSanto/  
Primary Examiner, Art Unit 3763